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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,747	02/22/2002	Marcus D. Ballinger	402E-476112US	6369

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EXAMINER

GAMETT, DANIEL C

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,747

Applicant(s)

BALLINGER ET AL.

Examiner

Daniel C. Gamett

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-68 is/are pending in the application.
- 4a) Of the above claim(s) 49, 50 and 52-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-48, 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application, Amendments, and Claims

1. The amendment of 03/30/2005 has been entered in full. Claims 1-39 are cancelled. Claims 40-68 are pending.
2. Applicant's election with traverse of claims 40-48 in the reply filed on 03/30/2005 is acknowledged. As the subject matter of newly entered claims 40-48 corresponds to original claims 14-17 and 34-39, which were all in Group I of the requirement for restriction/election mailed on 12/27/2004, the election of claims 40-48 is accepted as being responsive. Furthermore, as claims 40-48 are directed to a single heregulin variant, the requirement for election of species in the 12/27/2004 Office Action is moot and therefore withdrawn. The traversal is on the ground(s) that all pending claims can be examined in the present application without serious burden. This is found persuasive in part. Claim 51 can be grouped with claims 40-48 because it would have been included in Group I of the requirement for restriction/election mailed on 12/27/2004. Claims 49 and 50, however, recite a method of producing heregulin variants, exactly as in original claims 18 and 19 (Group II), which is distinct from the elected invention for reasons made of record in the 12/27/2004 Office Action. Likewise, claims 63-68 are drawn to the method of determining whether a sample contains an ErbB receptor, originally recited in claim 27 (Group V), which is distinct from the elected invention for reasons made of record in the 12/27/2004 Office Action.
3. Newly submitted claims 52-62 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 52-62 are drawn to a

Art Unit: 1647

method for binding an ErbB receptor. No such method was recited in the claims that were the subject of the 12/27/2004 Office Action. Furthermore, the elected Inventions of claims 40-48, and 51 (Group I) and the invention of claims 52-62 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of Group I, which includes nucleic acids, vectors, cells, and a method of producing a heregulin variant, can be used in materially different processes from that of claims 52-62, nucleic acid hybridization for example.

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 52-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 49, 50 and 63-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/30/2005.
6. Claims 40-48 and 51 are under examination.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

Art Unit: 1647

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 40-48, and 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14-17, 20 and 27-32 of U.S. Patent No. 6,136,558. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons: Both sets of claims recite identical heregulin variants. Claims 27-32 of U.S. Patent No. 6,136,558 are drawn to the heregulin variant polypeptide; instant claims 40-45 are drawn to the nucleic acid encoding the polypeptide. As the polypeptide was derived by site-directed mutagenesis of a known nucleic acid sequence (SEQ ID NO: 93), the patented polypeptide sequence renders the encoding nucleic acid obvious. Furthermore, the patented polypeptide cannot be made without use of the instantly claimed nucleic acid. Therefore, the polypeptide of 6,136,558, claims 27-32, and the nucleic acid of instant claims 40-45 are separately unpatentable. It is further noted that instant claim 40 and claims 1 and 27 of 6,136,558 each include the limitation wherein "said heregulin variant comprises a portion that is at least 70% identical to the portion from about residue 175 to about residue 230 of native human heregulin- β 1 (SEQ ID NO: 93)". Thus the only species of heregulin variant defined by instant claim 40 (and claim 27 of '558) that would not

Art Unit: 1647

also fall within the scope of claim 1 of '558 would be a heregulin that has none of the specific amino acid substitutions recited in claim 1. Patent 6,136,558 has claims to heregulin variant polypeptides (claim 1), the nucleic acids that encode them (claim 14), a vector comprising the nucleic acid (claim 15), a host cell comprising the vector (claim 16), a method of producing a heregulin variant comprising culturing the host cell (claim 17), and a composition comprising the heregulin variant (claim 20). Thus, instant claims 40-48 and 51 logically might have been included in 6,136,558. Claim 51 is drawn to a composition comprising the heregulin variant of claim 40 and a pharmaceutically acceptable carrier. Said composition is obvious over 6,136,558, claim 27, especially in view of claim 20, which is drawn to a composition comprising a genus of heregulin variants encompassing the variant of instant claim 51 and 6,136,558, claim 27. Therefore, issuance of a patent to the instant claims in the absence of a terminal disclaimer over 6,136,558 may result in an improper extension of the "right to exclude" granted by a patent and may result in possible harassment by multiple assignees.

Conclusion

9. No claims are allowed.

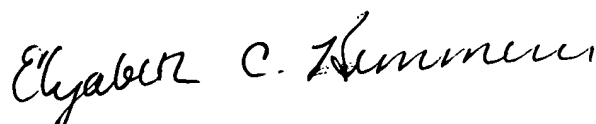
Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
13 May 2005



**ELIZABETH KEMMERER
PRIMARY EXAMINER**